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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE TO DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF THOMAS KINNEY, M.D., ANNE CHRISTINE ROBERTS, M.D., AND SANJEEVA KALVA, M.D.**

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Thomas Kinney, M.D., Anne Christine Roberts, M.D., And Sanjeeva Kalva, M.D. ("Motion" or "Mot.") [Doc. 7296]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and Daubert ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

At trial, the jury must decide whether Bard should be held accountable for marketing its IVC filters without first properly testing its filters for safety, for selling its

filters despite an unacceptable safety profile, and for failing to disclose to doctors that these devices had an alarmingly high complication rate—thus putting patients at risk of serious injury and death. Bard's liability hinges not only on duties of care created by federal regulations and Bard's own internal standards, but also its interference with physicians' obligation to obtain informed consent from their patients. Bard's liability also depends on the feasibility of conducting the appropriate studies based on what was known or knowable at the time. To sort through these complex issues, the jury will need to hear from qualified experts.

Drs. Kinney, Roberts, and Kalva are interventional radiologists. They have decades of experience implanting and removing IVC filters and have published dozens of studies on IVC filters and complications. Their testimony is especially helpful to the jury because they had first-hand knowledge of the defects in Bard's Recovery and G2 line (G2, G2X, and Eclipse) of IVC filters. Dr. Kalva's experience with the Recovery filter while a Massachusetts General Hospital and his efforts to alert Bard to a safety problem with the Recovery fell on deaf ears. Without support from Bard, Dr. Kalva and his colleagues conducted and published their own study showing an alarmingly high rate of complications. Combined, the experts have specialized knowledge in engineering, clinical studies, and medical standards for informed consent. They will explain to the jury what studies Bard could have done to identify defects in its filters and what information Bard should have disclosed to physicians so they, in turn, could recommend the use of another IVC filter or alternative treatment options for their patients.

Nevertheless, Bard moves to exclude these qualified experts based on: their alleged lack of qualifications; for relying on a foundation of internal company documents and deposition testimony which Bard alternatively alleges is either too selective or too detailed; for offering opinions about physicians' reasonable expectations of the contents of warnings; and, for expressing opinions the experts will not give at trial. In attacking the experts, Bard selectively distorts their testimony as well as the relevant case law. Drs. Kinney, Roberts, and Kalva are eminently qualified; their testimony is both helpful and

necessary to aid the jury in deciding Bard's liability. For the reasons below, Bard's motion should be denied.

II. BACKGROUND

A. The Experts' Qualifications

Drs. Kinney, Roberts, and Kalva ("the Experts") are renowned board-certified interventional radiologists. They specialize in treating patients with deep vein thrombosis and pulmonary emboli—life threatening complications. Their practice includes caring for patients who have, or will be receiving, inferior vena cava ("IVC") filters. All three Experts are leaders in the field of interventional radiology, lecturing on the benefits, risks, and use of IVC medical devices in patients. Over the past three decades, the Experts have published dozens of studies on IVC filters and are frequent invited lecturers on these devices. The Experts were among the first physicians to notify Bard of complications from its Recovery and G2 filters; their subsequent studies on complications of these devices led to additional published research on the issue by others in their field.

Thomas Kinney, M.D., M.S.M.E. is a Professor of Clinical Radiology and Vascular & Interventional Radiology at the University of California San Diego Medical Center, where he has taught for 17 years. He also has a Master of Science in Mechanical Engineering. Dr. Kinney is a Fellow of the Society for Vascular and Interventional Radiology in the U.S. and in Europe. He has served on the Editorial Board of the Journal of Vascular and Interventional Radiology; he has published over 90 peer-reviewed articles and more than 50 abstracts, and authored chapters in several medical textbooks, delivering over 130 invited lectures.

Since 1995, Anne Roberts, M.D. has served as Professor of Clinical Radiology and is Chief of Radiology at University of California, San Diego Medical Center. She is a Fellow of a dozen professional societies—most notably, the Society of Interventional Radiology, where she served as President. In this capacity, she helped develop standards of practice in IVC filter placement and informed consent standards. Dr. Roberts has

published over 100 peer-reviewed articles, 91 abstracts, and has authored more than 75 textbook chapters. She also worked for the FDA in the Office of Device Evaluation.

Sanjeeva Kalva, M.D. is Chief of Interventional Radiology at University of Texas Southwestern Medical Center in Dallas. He also heads up the hospital's IVC Filter Working group. Dr. Kalva is a member of the Society of Interventional Radiology and serves on its Standards of Practice Committee, updating procedures for IVC use and informed consent. He has published more than 100 peer-reviewed papers, many of which concern IVC filters. *See* Experts' CVs at App. B of Court Dkt. 7301, Def. Ex. G.

All three Experts have scientific and technical knowledge of the functional performance and use of IVC filters in the clinical setting. They have also personal experience with the failures of the Bard Recovery and G2 line of filters. Years prior to this litigation, Dr. Kalva observed a rapidly occurring and unexpectedly high number of safety issues with Bard's Recovery IVC filter while treating patients at Massachusetts General Hospital. He reported his concerns to Bard and sought help with a study to assess the safety issue he and others were observing in their patients; Bard declined to provide help. Court Dkt. 7301, Def. Ex. G, Rpt. at ¶¶ 256-258. Dr. Kalva and his colleagues took it upon themselves to conduct their own study without Bard's support and published their findings. The study showed the Bard Recovery had an unacceptable safety profile with a much higher rate of failures (migration and fractures) than Bard disclosed to physicians. *Id*. at ¶¶ 259, 254. Despite the findings, Bard never warned about the Recovery's unacceptable safety profile/increased failure rate or the flawed testing standards it used to assess the safety of its Recovery filter. Many of Bard's defective IVC filters remain implanted in patients today, posing a risk of serious injury or death.

B. Report Preparation

The Rule 26 report prepared by Drs. Kinney, Roberts, and Kalva is a collaborative effort by all three Experts. In developing their opinions, the Experts relied on a combination of data, including: relevant published medical literature on IVC filters; the expert reports of Drs. Kessler, Ritchie, and Betensky; Bard's internal source documents;

depositions of Bard employee witnesses; and, their personal clinical experience studying and placing Bard's and other IVC filters in patients. App. A and Schedules 1-5 of Court Dkt. 7301, Def. Ex. G. of Court Dkt. 7301, Def. Ex. G. They wrote their report without input from Plaintiffs' counsel. Ex. 1, Kinney Dep. at 299:25-300:8. The Experts undertook their own exhaustive searches of the enormous volume of published medical literature on IVC filters—without input from counsel—and culled them down to determine which articles were the most relevant to their opinions. Ex. 2, Kalva Dep. at 62:3-25; 65:1-66:18; Ex. 3, Roberts Dep. at 17:20-18:6; 18:17-19:8; 92:11-93:24.

III. ARGUMENT

A. The Experts Reasonably Based Their Opinions, In Part, On Bard's Documents, On Bard's Employee Testimony and The Experts Did Not Rely Solely On Other Experts' Reports, and They Independently Reviewed the Other Experts' Underlying Data for Verification.

1. The Experts may reasonably base their testimony in part on Bard's documents and employee testimony.

Bard first accuses Drs. Kinney, Roberts and Kalva of violating Rule 703 for considering internal documents produced by Bard and employee witness testimony. Bard maintains that because the Experts do not rely on internal company documents in the course of their professional research or clinical practice, the evidence is not of the type of "facts or data experts in their field would reasonably rely on" required by Rule 703 to form an opinion. This argument is spurious. It is the information in these documents that is relevant to the unacceptable safety profile of Bard's IVC filters. It is entirely reasonable for these experts to consider and rely upon the information in Bard's own documents that demonstrate an unacceptable safety profile.

At issue in this case is whether Bard was negligent in the design/manufacture/sale of its IVC filters and whether the company adequately warned physicians, hospitals and patients once it became aware of the unacceptable safety profile of its filters. Ironically, Drs. Kinney, Roberts, and Kalva directly sought this information from Bard when they became concerned about the safety of the Recovery and G2 filters. As Dr. Kinney explained, "[Dr. Roberts and I] were promised that the [Bard] retrieval filter would have

the same sort of performance characteristics that our permanent devices had. And unfortunately, as the experience – as the clinical experience accrued with the retrieval filters, we were finding out that that assumption was not true…" Ex. 1, Kinney Dep. at 74:24-75:4. As a paid consultant to Bard, Dr. Kinney expected that the company would tell him what it knew; indeed, he was advising and training his colleagues on the use of Bard's filters based on the company's representations that the devices were safe and effective. *Id.* at 196:23-197:1-22; 310:20-311:9; 314:7-10. Indisputably, the Experts—and the entire community of interventional radiologists—would have welcomed the information Bard produced in this litigation to avoid exposing their patients to these harmful devices**;** injuries would have been prevented, and lives would have been saved.

The law requires all experts to testify on technical matters within the confines imposed by rules of evidence and procedure, and typically based in part on information provided to them by parties in the course of discovery. Rule 703 does not bar experts from considering relevant and reliable evidence they have been made aware of simply because Bard has chosen to withhold internal safety documents and/or safety information from the very doctors who implant their IVC filters.

2. <u>The Experts are permitted to base their opinions, in part, on other experts' testimony.</u>

Among other sources of evidence, Drs. Kinney, Roberts, and Kalva reviewed the Rule 26 report by Dr. Kessler and other experts, and they carefully scrutinized the experts' underlying data in developing their own opinions. Misleadingly, Bard cherry-picks sound bites out of context from the Experts' deposition testimony to make it appear that they adopted Dr. Kessler's opinions uncritically and "parroted" them as their own opinions in violation of Fed. R. Evid. 703. Bard mischaracterizes both the factual record and the law.

In complex cases, where the parties offer opinions of multiple experts, it is not uncommon for an expert to base an opinion, in part, on the testimony of other expert witnesses with more specialized knowledge. *In re Toyota Motor Corp. Unintended*

Acceleration Mktg., Sales Practices, and Prods. Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). Such testimony is admissible as long as the expert does not merely act as a conduit for the other expert's opinion, *id.*, and provided that the record shows that the expert independently evaluated the evidence supporting the other expert's opinion. *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 556 (C.D. Cal. 2014). The report of Drs. Kinney, Roberts, and Kalva satisfies both requirements.

First, the Experts do not rely solely on the opinions of Dr. Kessler, Ritchie, and Betensky. Besides reviewing thousands of pages of documents and testimony, the Experts culled through a large volume of medical literature on IVC filters in compiling their own reference list of relevant articles. They also cited their own published, peer-reviewed research and that of their colleagues. They combined this data with their own personal clinical experience with IVC filters, including their interactions with Bard at the time they discovered defects in the filters. The Experts conclude that their assessment of the safety and performance problems with the Bard IVC filters and labeling of Bard's filters is similar to that of Dr. Kessler and other experts. Their agreement with these opinions does not hinder the reliability of their analysis because it is consistent with their own research. *See In re Toyota*, 978 F. Supp. 2d at 1071 (expert's opinion was admissible because he reviewed other types of data, not solely other experts' opinions). There is simply no support for Bard's assertion that the Experts acted as mere "conduits."[1]

Second, the record is clear that the Experts independently evaluated every source document cited in the reports of Drs. Kessler, Ritchie, and Betensky to ensure coherence with their analyses. Besides conducting his own review of the scientific literature, Dr.

[1] Bard also launches a "straw man" attack on the Experts for having counsel prepare "Schedules" as addenda to their report. The schedules list materials cited by the Experts organized by issue. Mot. at 4 n. 1. Bard concedes the Experts did not rely on these compilations for their opinions; after drafting the report, they requested counsel to create these schedules for ease of organization. Ex. 2, Kalva Dep. at 60:7-20. The Experts will not refer to the schedules when testifying, although they may be of assistance to the Court in referring to categories of source documents.

Kinney looked at Bard's entire 510(k) submission and the studies cited in it, as well as "all the documents that were listed by Dr. Kessler" and noted that these sources were consistent with the complications with the Bard filters that he and Drs. Roberts and Kalva had observed in their patients. Ex. 1, Kinney Dep. at 76:3-77:21. Dr. Kalva testified that he reviewed every document cited in the reports of Drs. Kessler, Betensky, and Ritchie. Ex. 2, Kalva Dep. at 165:2-16. He read them to determine whether they supported his opinions. *Id.* at 152:3-14. And Dr. Roberts testified that she felt "quite comfortable" with the expert reports she reviewed after reviewing the source materials. Ex. 3, Roberts Dep. at 115:13-116:5.

The Experts' thorough evaluation of the documents supporting the opinions of Drs. Kessler, Ritchie, and Betensky therefore avoids any reliability concerns the Court may have about relying, in part, on these other experts' reports.[2] *See In re ConAgra Foods, Inc.*, 302 F.R.D. at 556 (finding expert's testimony admissible because she has reviewed the other expert's underlying data and other relevant information).

B. The Experts' Testimony Will Be Helpful to the Jury.

Drs. Kinney, Roberts and Kalva will testify about the safety and performance failures in Bard's IVC filters, the studies documenting those failures, and the adequacy of information Bard gave to physicians. This testimony will assist the jury because they have applied their knowledge to complex scientific information, as well as medical standards for informed consent. Bard nevertheless attacks the details of the Experts' reports, characterizing them as "editorializing," "plaintiff-slanted summaries" and

[2] Bard suggests that because the opinions by Drs. Kessler, Betensky, and Ritchie and the Bard documents cited in their reports are "unreliable," so, too, are the Experts' opinions. Absent from Bard's motion is any argument or evidence that the Bard documents Dr. Kessler and others cite are untrustworthy or that Bard's employee witnesses lied under oath. In fact, Bard had ample opportunity at the Experts' depositions to present documents and testimony to contradict the evidence cited in their reports, but they did not. Bard cannot now argue that the discovery they produced in litigation is "unreliable" and taints the entire foundation for the Experts' opinion.

"commentary" to argue that narratives are not permissible. Bard distorts what the Experts intend to say at trial.

First, the Experts will not offer any opinions or comments on Bard's state of mind. Instead, they will focus their testimony on what Bard knew or should have known at the time about its IVC filters' safety and performance issues, the available scientific literature, and what doctors in their field expect a company to communicate to them to determine whether to use a Bard filter and to ensure they obtain adequate informed consent about the risks and benefits of Bard filters.

Second, Bard's own documents provide the foundation necessary under Rule 702 for the Experts to express their opinions. These documents set forth a chronological explanation of what Bard knew when it was confronted with safety signals and the reasons why Bard's filters were failing. Without these details, Bard would surely have argued that the Experts lack an adequate foundation for their opinions. *See, e.g.*, *City of Pomona v. SQM North America Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014) (noting that an opinion based on undocumented information is the "antithesis" of reliable expert testimony). Jurors cannot possibly sift through thousands of pages of technical documents from Bard's files and understand what they mean. That is the role of the Experts. The Rules of Evidence do not prohibit the Experts from providing helpful context and explanation to the jury in deciding issues of liability.

1. Bard's Objection to How the Experts Selected Documents Is Unfounded.

Bard complains that the Experts focus only on a small subset of documents "arranged to tell the plaintiffs' story" instead of citing all 1.5 million documents (and presumably, explaining each of them). As described above, the Experts reviewed Bard employee depositions, all of the source materials cited in the Kessler, Ritchie, and Betensky reports, and conducted their own literature searches. The Experts decided which documents to include as references in their report. *See* Ex. 2, Kalva Dep. 62:14-25; 75:8-16.

Although Bard hints that the remainder of Bard's production is rife with documents that undermine the Experts' opinions, they do not identify them in their motion. Nor did they do so at the Experts' depositions, despite the experts' repeated requests for such examples:

> Q: As part of your methodology in this case, did you ignore data that weighed against your opinions that Bard's filters are defective?
>
> A: I don't think so.
>
> Q: Would you agree that if you did ignore data that weighs against the opinion that Bard's filters are defective, that you would be applying the same level of intellectual rigor in this case as you apply in your private practice as a researcher and clinician?
>
> A: I would say that I'm always willing to look at data. If you have some data to show me, I'd be happy to look at it and opine about it.

Ex. 1, Kinney Dep. at 72:22-73:9. *See also* Ex. 3, Roberts Dep. at 110:12-23 ("If you have data that we didn't consider, I'll be more than happy to look at that data and make sure that it's, you know, part of any further work that we do on this case.").

Moreover, if Bard believes there are other documents that contradict those the Experts cite, the proper remedy is cross-examination, not exclusion. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

2. Testimony regarding internal company documents is helpful to the jury when the facts are complex.

Even if the Experts' reports describing Bard's documents were construed as "narrative," an expert may provide factual summaries of corporate documents as long as the testimony relates to complex matters that would assist the jury. Plaintiffs incorporate by reference the legal authority for offering such testimony in Section D of Plaintiffs' Omnibus Memorandum.

A juror cannot be expected "to determine intelligently and to the best degree" the concepts of device failure and test methods, such as fatigue testing, device fracture, load stress, and migration resistance without assistance from the Experts. *See, e.g., U.S. v.*

Findley, 301 F.3d 1000 (9th Cir. 2002) (defining standard for determining whether expert witness testimony is needed to assist the jury). Drs. Kinney, Roberts, and Kalva will not testify solely as "summarizers" of documents. Instead, their proposed testimony about Bard's internal documents will provide a contextual and factual foundation for their opinions as interventional radiologists with specialized knowledge of IVC filters and how IVC filters are intended to function in the human body. These matters are well beyond the knowledge of a lay juror, and courts find such testimony helpful.

3. Objections to "narratives" are properly raised at trial, not in a *Daubert* motion.

Bard's objection to what it calls "narrative" testimony is also premature. Courts in other MDLs have rejected similar *Daubert* challenges raised by defendants because it is a decision made at the time of trial. "The objection that testimony is 'narrative' is an objection to form, foundation or responsiveness, and must be presented at trial—as no question is now before the Court to which objection can be made." *In re Actos (Pioglitazone) Products Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014). MDL Judge Herndon agreed:

> As to defendants' argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would be helpful to the jury… Such matters will be decided at trial in context specific situations and will be ruled on then.

In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011).

In *Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013), the defendants sought to exclude the testimony of Dr. Kessler (one of plaintiffs' experts in this litigation) on similar grounds, arguing that he "improperly assumes the role of Plaintiffs' advocate" and "regurgitated" a narrative. The court held that testimony about underlying facts provided useful context and may otherwise be challenged at trial. "To the extent the facts relied upon by [the expert] are relevant and

not cumulative," the expert witness "may include them in his testimony… Defendant may object at trial if [the expert] appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions." *Id.* at *2.

C. The Experts Are Qualified to Opine about Information They Expect an Adequate Warning to Include.

Bard maintains that no expert—including Drs. Kinney, Roberts, and Kalva—may testify that they and their colleagues reasonably expected Bard to provide accurate and up-to-date information to physicians about the risks of its IVC filters. Specifically, Bard contends there is no written standard that defines what a "reasonable physician" would do with this information if they had it. Bard further argues that the Experts have not furnished a study to support their conclusions that the community of interventional radiologists find Bard's IVC filter warnings to be inadequate. Without such evidence, Bard concludes, there is no factual basis for their opinions. Bard's arguments are entirely without merit.

The factual record in this case is clear that Bard knew its IVC filters had an unacceptable safety profile and were failing at a much higher rate than its warnings stated. Bard also knew from interviews it solicited from surgeons and interventional radiologists that physicians expected IVC filters to perform as represented to them, and that any failure of its filters was unacceptable. Yet, Bard never warned doctors about the unacceptable migration, tilt, and fracture problems it was experiencing with the Recovery and G2 filters. Bard also ignored concerns expressed by Drs. Kinney, Roberts, and Kalva and other physicians whose patients experienced life-threatening complications from the devices' failures.

What a reasonable physician expects to be told about the potential risks of IVC filters is not subjective or limited by the facts of a specific case, as Bard suggests. This expectation is an integral component of obtaining informed consent—a universal standard in the practice of medicine. In explaining the rationale for their opinions about what a reasonable physician needs to know about the risks of Bard's IVC filters, the

Experts cite the published ACR/SIR Practice Guideline on Informed Consent for Image-Guided Procedures. Court Dkt. 7301, Def. Ex. G, Rpt. at ¶ 8. As the ACR/SIR guidelines state, "prudent and ethical medical practice" requires physicians to make sure the patient has "every opportunity to understand the treatment or procedure the patient is to receive and its reasonable risks, benefits, and alternatives; to have all questions answered; and to fully consent to the treatment and procedure." *Id.* at ¶ 8. Informed consent is critical in caring for patients who are candidates for IVC filters. It is therefore incumbent on the manufacturer to provide "current and *up-to-date* safety information" regarding the frequency, severity, and types of complications associated with each filter. *Id.* at ¶ 9.

As Dr. Roberts explained, if physicians are unaware of this information, they are unable to consider using another filter brand, they are unable to consider other treatment option, they are unable to disclose this information to their patients, and are hindered in making "good decisions about how to take care of a patient." Ex. 3, Roberts Dep. at 300:1-15; 103:9-18. Even Bard's own regulatory affairs expert, Donna-Bea Tillman testified, "I think that physicians need to have enough information to understand the risks and the benefits in order to advise their patients… [a]nd to provide informed consent." Ex. 4, Tillman Dep. at 292:1-14. Dr. Clement Grassi, another Bard expert, agrees. Ex. 5, Grassi Dep. at 183:21-185:3. Bard's employees likewise agree that accurate information on risks and benefits of IVC filters is essential to informed consent. Ex. 6, Ganser Dep. at 208:2-22.

The informed consent doctrine is rooted in the fundamental medical principle that "a competent individual has a right to determine what shall be done with her own body." *Harbeson v. Parke Davis, Inc.*, 746 F.2d 517, 522 (9th Cir. 1984) (internal citations and quotations omitted). Citing no authority, Bard argues that the "reasonable physician" standard here is different from that of a medical malpractice case where the standard of care "is based on objective and verifiable standards and medical practice as it relates to a particular physician and patient." Mot. at 10, n.4. This is a false distinction.

The type of expert testimony required for a medical product liability case involving failure to warn is no different than in a medical malpractice case, particularly on the subject of informed consent. Both cases depend on medical testimony as to what type of information on risks and benefits a reasonable physician should know and disclose to the patient. And the foundation for a medical expert's opinion is the same, including professional guidelines, clinical experience and education, peer-reviewed literature, and interactions with colleagues in the relevant community. This is the ordinary methodology physicians use in making day-to-day medical judgments. *Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010).

Furthermore, one of Bard's own experts published a paper reflecting the medical community's agreement with the Experts' opinion that physicians reasonably expect manufacturers to provide complete and accurate information on the safety profile of IVC filters. Outside of litigation, Dr. David Feigal coauthored a paper published in the NEW ENGLAND JOURNAL OF MEDICINE urging medical device manufacturers to be more forthcoming in warning doctors about life-threatening malfunctions of implantable cardiac devices. Ex. 7, Ganser Dep. Ex. 518. "[P]hysicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining informed consent." *Id.* at 2309. The authors stressed, "From the perspective of physicians' and patients' expectations, corporate responsibility, and public perception, we believe that proactive communication policies, centered on the proper use of active and passive transparency, should be the norm."

Bard's employees and experts admit that a key issue in this case is doctors' and patients' expectations of the risks and benefit profile of Bard's filters. Christine Brauer, a Bard FDA expert, conceded, "I agree that it's important for a medical device manufacturer to understand healthcare professionals' expectations for performance of a product." Ex. 8, Brauer Dep. at 334:4-14. Indeed, Bard was keenly aware from its own Multidisciplinary Panel Focus Group that physicians who used IVC filters believed that a retrievable filter "is expected to perform just as well as a permanent filter," and that a

filter "should not migrate; no matter what the size of thrombus burden it captures." Ex. 9, Schultz Dep. Ex. 3 at BPVE-01-00617780-81. Bard cannot seriously argue that physicians' expectations of being adequately informed are irrelevant in this litigation.[3]

Finally, Bard improperly conflates the Experts' proposed testimony on the adequacy of Bard's label with opinions on ethical standards. Mot. at 10. However, Drs. Kinney, Roberts, and Kalva will not testify about ethical duties or ethics in general. They will limit their opinions to what information from Bard was necessary to obtain a proper informed consent on the risks of IVC filters, which happens to be an ethical responsibility doctors have to their patients.

D. The Experts Are Qualified to Express Opinions on the Performance and Safety Issues of Bard's IVC Filters and Inadequacies in Testing.

The Experts criticize the methods Bard used to test the resistance thresholds for migration and fracture. Court Dkt. 7301, Def. Ex. G, Rpt. at ¶¶59-77; ¶¶ 141-182. Bard moves to exclude their testimony on "bench top tests," arguing that the Experts lack expertise in conducting bench tests on IVC filters specifically. Bard downplays the Experts' considerable knowledge and experience with medical devices in general and the types of tests that manufacturers must perform to meet safety requirements. Bard also ignores the fact that for decades, the Experts have inserted IVC filters in countless patients, have removed filters that tilted, migrated, perforated and/or fractured, and published numerous papers describing complications with these devices.

Each of the Experts has specialized knowledge in the design, testing, and/or research of IVC filters and their functional performance. Dr. Kinney has a Master of Science in Mechanical Engineering and has designed medical devices. He was also a paid consultant for Bard, advising the company and training physicians on the use of its IVC filter. In addition, Dr. Kinney has served as Chair of data safety monitoring boards

[3] In fact, in its Answer, Bard raises "learned intermediary" as an affirmative defense. Bard thus denies liability to Plaintiffs on the grounds that they adequately informed physicians of the risks of its IVC filters.

for clinical trials involving other IVC filters. *Id.*, Rpt. at ¶¶ 23-24. He has published numerous studies and review articles on IVC filters, including IVC design function, as well as guidelines on behalf of the Society of Interventional Radiology (SIR) on the use of IVC filters. *Id.*, Rpt. Appx. B; Ex. 4, Kinney Dep. at 33:21-34:11.

From the beginning of her career, Dr. Roberts has been involved in the study of IVC filters. She has worked on clinical trials of IVC filters and served as Chair of the Data and Safety Monitoring board for Bard's Denali filter. She lectures colleagues and medical students on various aspects of IVC filters and has authored several published peer-reviewed articles on IVC filters. Court Dkt. 7301, Def. Ex. G, Rpt. at ¶¶ 40-41.

In his practice, while working at Massachusetts General Hospital, Dr. Kalva encountered safety issues with Bard's Recovery IVC filters. He and his colleagues conducted a study of their patients and found a high failure rate of Bard filters. *Id.*, Rpt. at ¶¶ 256, 257, 259. Since then, Dr. Kalva has published well over a dozen studies on the function, use, and complications of IVC filters. *Id.*, Rpt. Appx. B. Dr. Kalva is involved in developing a patent for an IVC filter design. Ex. 2, Kalva Dep. at 24:19-25:1.

Although the Experts are not offering opinions on FDA regulations, they are familiar with the regulatory requirements medical device companies must meet. For example, Dr. Kinney designed medical devices for physicians and participated in the preparation of 510(k) applications to the FDA. He also drafted language in both IFUs ("Information for Use") and labeling. Ex. 1, Kinney Dep. at 25:4-27:4; 42:3-16. Dr. Roberts worked from 1995-96 at the FDA, where she evaluated medical device submissions, including tests necessary for approval or § 510(k) clearance. She also drafted labels and understands what must be included in the contents of a medical device label. Court Dkt. 7301, Def. Ex. G, Rpt. at ¶ 36; Ex. 3, Roberts Dep. at 37:9-38:7; 40:15-23. Dr. Roberts' involvement with the agency continues; she has served on the FDA's circulatory device advisory panel and has met periodically with FDA officers regarding medical devices. *Id.* at 41:5-21. She has lectured physicians and students at the UCSD

School of Engineering on FDA regulations, procedures, and requirements for study design. *Id.* at 44:22-45:25.

"If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. An expert need not have "official credentials in the relevant subject matter" to provide testimony. *United States v. Smith*, 520 F.3d 1097, 1105 (9th Cir. 2008). Arguments that an expert's qualifications are "different or less impressive" than other experts go to the weight, not the admissibility, of the expert's opinions. *PSM Holding Corp. v. National Farm Financial Corp.*, No. CV 05-08891 MMM (FMOx), 2013 WL 12080306, at *10 (C.D. Cal. Oct. 8, 2013).

The Experts' testimony on the inadequacies of the testing methods used for Bard's IVC filters is relevant because it explains why Bard itself determined its filters had unacceptable risks and why Bard personally observed (and was aware of) such a high rate of tilt, migration, perforation and fracture of these devices in clinical practice. Bard's failure to disclose the reason for the high failure rates also prevented the Experts and their colleagues from giving their patients the option of consenting to alternative devices in their surgical procedures.

The Experts' broad knowledge of medical device performance testing, and their own clinical experience with Bard IVC filters qualify them as experts. Any criticism that the Experts lack direct experience performing bench studies on IVC filters is appropriate for cross-examination, but it is not adequate grounds for excluding their testimony.

IV. CONCLUSION

For the reasons stated above, Plaintiffs respectfully ask the Court to deny Bard's Motion.

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti